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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,351	07/10/2003	Gary Ruvkun	00786/423002	5214
21559	7590	03/03/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 03/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,351	RUVKUN ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 15-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7.10.2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election

1. Applicants' election without traverse of Group 1869, claim 14, drawn to a method of identifying a candidate compound that modulates fat metabolism by using a microarray in the reply filed on 1.5.2006 is acknowledged.

2. **Claims withdrawn** : Claims 1-13 & 15-29 corresponding to groups 1-1868 & 1870-7167 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. *Priority*

Applicants' claim for domestic priority under 35 U.S.C. 119(e), filed 11 July 2002, is acknowledged.

4. *Specification*

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

5. *Claim Objections*

Claim 14 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 14 depends from non-elected claim 12. Rewriting the claim in independent form is suggested to overcome this objection.

6. Claim 14, line 8, after the word 'cell' delete comma or ',' - a typographical error.

7. *Claim Rejections - 35 USC § 112* (first paragraph)

Enablement

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a candidate

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compound capable of modulating fat metabolism comprising: (a) contacting a specific cell with a candidate compound; (b) obtaining mRNA from said cell; (c) contacting a microarray having specific fat metabolism nucleic acids (???) with said mRNA; and (d) detecting an alteration in cellular mRNA levelcompound that modulates fat metabolism, does not reasonably provide enablement for a method of identifying a candidate compound capable of modulating fat metabolism using any cell and/or microarray that comprises at least 2 of the fat metabolism regulator nucleic acids or fragments thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number cell types and therefore varying microarray depending upon the cell type that is encompassed by the claims.

Since the cell type (i.e. nematodes, mammalian, etc) will determines the nature of mRNA extracted and therefore the nature of the microarray comprising the numerous fat metabolism regulator nucleic acid will vary accordingly, and the guidance provided is sparse with respect to any cell type and therefore any microarray. The instant specification also lacks any guidance or specific example(s) of the nature of the potential inhibitors. The prior art is silent too with respect to the specific properties of the inhibitor compounds, and one skill in the art will be left with high unpredictability in view of the lack of knowledge and/or guidance of the instant disclosure as applied to the claimed method of identifying a candidate compound that modulates fat metabolism in any cell type

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using any microarray comprising any set of fat metabolism regulatory nucleic acids.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, identifying a candidate compound that modulates fat metabolism in any cell type using any microarray comprising any set of fat metabolism regulatory nucleic acids is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue in using the modified enzyme in the method claimed. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. ***Claim Rejections – 35 USC § 102***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 14 is rejected under 35 U.S.C. 102(e) as being anticipated by Gu et al. [US 2004/0197766 A1, July 5, 2001].

Claim 14 is drawn to a method of identifying a candidate compound capable of modulating fat metabolism comprising: (a) contacting any cell with a

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candidate compound; (b) obtaining mRNA from said cell; (c) contacting a microarray having any fat metabolism nucleic acids with said mRNA; and (d) detecting an alteration in cellular mRNA level of a fat metabolism regulator nucleic acid molecule in said cell contacted with said compound compared to a control cell; wherein said alteration identifies the candidate compound that modulates fat metabolism.

Gu et al. teach a cell-free or cell based method for identifying modulator compounds (paragraph 0010), which bind to and/or activate or inhibit (modulate) the activity or expression of 58128 protein (a G-protein coupled receptor protein (GPCR), plays a role in obesity and is therefore related to fat metabolism**) or mRNA, wherein the level of cell expression is compared in the presence or absence of the modulator compound, and wherein the level of protein or mRNA can be determined by any of methods described herein (paragraph 0036, as well as 0070, 0073, 0093), or the cited patent, which includes hybridization of DNA or RNA to high density arrays (or microarray) containing hundreds or thousands oligonucleotide probes (paragraphs 0082, 0083). The reference teaches all the claim limitations, and therefore anticipates the claim.

[Note: (1) Nucleic acid detection by Microarray/Chip technologies are well documented techniques and described in paragraph 0110-0111 of US 2003/0157486 A1, and references therein, for example].

**See abstract – Yip et al. Life Sciences (2000) 66(2): 91-103.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am – 5.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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February 22, 2006